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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,992	02/19/2003	Raffael Lahav	D01/200	2589
7590	01/11/2005			
D Graeser The Polkinghorns 9003 Florin Way Upper Marlboro, MD 20772			EXAMINER OH, SIMON J	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/018,992	Applicant(s) LAHAV ET AL.	
	Examiner Simon J. Oh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-90 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 40-90 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time and affidavit under 37 C.F.R. § 1.131, all received on 24 August 2003.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1 and 7 under 35 U.S.C. 112, second paragraph, as being indefinite is rendered moot with the cancellation of those claims.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-3, 5, 7-10, 14, 15, 17-19, 21-25, 29, 30, 32, 33, 36, and 37 under 35 U.S.C. 102(b) is rendered moot with the cancellation of those claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 40-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietrich *et al.* in view of Lundberg *et al.*

The Dietrich *et al.* patent discloses benzimidazole derivative compositions comprising a core and neutralized enteric coatings that are in direct contact with the core (See Page 7, Lines 1-10). Specific benzimidazole derivatives that are deemed suitable for the disclosed compositions include omeprazole, pantoprazole, lansoprazole, and salts thereof (See Page 7, Lines 12-15; and Example 3). One or more film formers may be applied to the core, where the film formers are neutralized enteric coatings (See Page 7, Lines 6-7 and Claim 1). Various materials may be used for the enteric coating, including cellulose acetate phthalate, cellulose acetate trimellate, and hydroxy propyl methyl cellulose succinate. Additives such as softeners may be added to these coatings (See Page 9, Lines 9-21). The enteric coating is preferably applied as an aqueous dispersion and treated with a base (See Page 10, Lines 13-20). Suitable bases that may be used to neutralize the enteric coating include sodium hydroxide and ammonium hydroxide (See Page 10, Line 21 to Page 11, Line 2). The resulting pH of the neutralized coating will usually range from 4 to 8, although high values are not considered to be disadvantageous (See Page 11, Lines 4-10; and Page 13, Line 10). The examples provided in the reference show instances where the cores may be formed by wet granulation or by coating the active ingredient over a neutral core, with the enteric coating applied directly over the core. Hydroxypropyl methylcellulose phthalate is not used in any of the examples provided (See Examples 1-4, and Examples 5 in particular).

Claims 58-60, 76-78 contain limitations reciting a percentage value of the degree of neutralization of an enteric coating material. It is the position of the examiner that such properties are inherent in an enteric coating material of the prior art when the pH of an enteric

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coating is adjusted to a particular value using known methods. Therefore, these claims are considered to be obvious in view of the prior art.

The Dietrich *et al.* reference does not teach the use of citric acid esters or phthalic acid esters as plasticizers.

The Lundberg *et al.* patent teaches enteric-coated compositions of benzimidazole derivatives (See Abstract; and Claim 1). Polymers suitable for use as enteric coatings in the disclosed compositions include cellulose acetate phthalate, cellulose acetate trimellate, and hydroxy propyl methyl cellulose succinate. Suitable plasticizers for use with these materials include citric acid esters and phthalic acid esters (See Column 7, Lines 27-53).

It would be obvious to one of ordinary skill in the art to combine the teachings Dietrich *et al.* and Lundberg *et al.* into the objects of the instant application. The prior art references both disclose enteric-coated compositions of benzimidazole derivatives, and are therefore pertinent for application against the instant claims. Although the Lundberg *et al.* patent contains undesirable elements that the instant application seeks to overcome, it is the position of the examiner that certain portions of the prior art can still be used without introducing the drawbacks that the instant application seeks to avoid. Lundberg *et al.* is relied upon for the disclosure regarding suitable plasticizers for use with the disclosed enteric coatings, many of which are also cited in Dietrich *et al.* as being suitable for use as neutralized enteric coatings. It is the position of the examiner that one of ordinary skill in the art can use the plasticizers disclosed in Lundberg *et al.* in the neutralized coatings of Dietrich *et al.* with a reasonable expectation of success in forming stable benzimidazole derivative compositions. The examiner does not see claim

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limitations drawn to the inclusion of a poloxamer in the core as being a patentably critical feature of the instantly claimed invention. Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 24 August 2003 have been fully considered but they are not persuasive.

The examiner has considered the applicant's affidavit under Rule 131, but it is not considered to be persuasive. The applicant's response made reference to the alleged unsuitability of the Dietrich *et al.* reference as prior art. However, this is not mentioned anywhere in the applicant's affidavit. No original drawings or records, or photocopies thereof have been submitted with this declaration, as required under 37 C.F.R. § 1.131, and no satisfactory explanation for their omission has been given. No evidence with a verifiable date has been given. As such, the applicant's declaration is not found to be persuasive with respect to establishing reduction to practice.

The examiner does not agree with the applicant's interpretation of the prior art. The embodiments disclosed within the prior art are not solely restricted to using multiple coatings. An embodiment exists where one coating of a film former, being a neutralized enteric coating, is placed over the tablet core. Such a film former can be used, and therefore, is not necessarily required for use, as a base coating for other enteric coatings. Although this is not a preferred embodiment of the prior art, this embodiment is considered by the examiner to be fairly taught by the prior art. See MPEP § 2123.

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Furthermore, the majority of the independent claims are drawn to compositions that comprise a substrate and an enteric coating layer. The open language of the instant allows for the inclusion of other components, including intermediate layers. Although the need for such layers would be obviated, that does not actively exclude them from the instantly claimed compositions.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1615

sj0

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600